Plastic Containers: What could be leaching into our food?

M.J. Kolodziejski*, Principal Chemist; E.J. Tullo, Principal Chemist; J.M. Roark, Group Leader; A.J. Miller, Chemist; W.B. Atkins, Senior Chemist

Abstract

Purpose: Many foods and drug products that we consume are packaged in plastic containers. The purpose of this study was to generate extractables profiles for black crystalline polyethylene terephthalate (PETE) microwave food trays, clear, colorless black crystalline polyethylene terephthalate (CPET) microwave trays, and polycarbonate (PC) reusable beverage containers. These profiles are used to establish the identification and approximate concentration of compounds that could potentially leach from container/closure systems into food or drug products.

Methods: Each container component was cut into approximately half-inch square so that a total surface area to volume ratio (SA/V) of 200 cm²/L was achieved, as per USP-<88> Biological Reactivity Test. Three extraction solvents were used and volume of each solvent was chosen so each container was nominally 5% saturated with each solvent. Each extraction solution was subsequently analyzed by selected ion GC/MS for semi-volatile organic compounds, and polymeric/basic chromatography Mass Spectrometry (LC/MS) for non-volatile organic compounds. The LC/MS analysis was performed using two modes of ionization: atmospheric pressure chemical ionization (APCI-), electrospray ionization in the positive mode (ES2), and atmospheric pressure chemical ionization in the negative mode (ES-). In addition, Headspace Gas Chromatography Mass Spectrometry (GC/MS) analysis was performed on samples that were not exposed to reflux extraction. For the determination of metals and new extractables, ICP-OES analysis was performed on acid-digested solution of each component.

Conclusions: A complete extractables profile was generated for each component tested. This same methodology is also used to characterize extractables compounds for pharmaceutical container closure systems, as required by the FDA’s guidance document, “Container Closure Systems for Packaging Human Drugs and Biologics.”

Objective

The objective of the study is to provide an extractables profile for common food container components. Similar techniques can be applied to pharmaceutical container closure systems to provide initial characterization of potentially leachable components.

Methods and Materials

Sample Preparation:

Reflux: For each solvent, an approximately 30 cm² portion of each component was cut into approximately one cm pieces prior to placement into a 50-mL round-bottom flask for reflux. Three reflux solvents were used, including water, hexanes, and ethan. Approximately 18 mL of solvent was added to each sample. A cold-cycled condenser was attached prior to heating. Each was heated to boiling and continued to boil for 30 minutes. After 30 minutes, samples were cooled prior to transfer to 20-mL volumetric flasks. Each was brought to volume with the appropriate solvent and mixed.

LC/MS Non-volatiles: A 0.9 mL portion of each was removed for LC/MS analysis. Samples were analyzed by LCMS Trap, utilizing ES+-, ES-, and APCI+ ionization with external standard quantitation. For each LC/MS mode, the response for reserpine was used for system suitability determination and sample quantitation. A residue reporting limit standard was prepared at 1 µg/mL to be used to determine the reporting threshold. Any compound with a peak response above the reporting limit was quantitated. For each mode of ionization, a C18 reversed-phase gradient separation ranging from 10% organic to 100% organic was utilized. Mobile phase modifiers were added to facilitate ionization in each mode. For each analysis, a scan from 50 to 1500 m/z was performed.

GC/MS Volatiles: To the ethanol and hexane solutions, 1.0 mL of phenanthrene-d10 internal standard solution was added for GC/MS analysis. Water samples were vortex-extracted with an equal volume of methylene chloride and concentrated to dryness. Each extraction solution was subsequently analyzed by GC/MS analysis. Selection of the internal standard for GC/MS semi-volatile analysis. A portion of each methylene chloride layer was analyzed by GC/MS using direct-injection analysis with internal standard quantitation. A 0.5% phenethylalcohol analytical column was utilized using a temperature-programmed elution. Each sample was scanned from 50 to 550 u.

Plastic Containers: What could be leaching into our food?

References

2. NIST 50K Database. Version 2.0, 2001